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Indian Standard

SPECIFICATION FOR SPECIAL PURPOSE SYRINGES

PART 6 IRRIGATION SYRINGE

- 1. Scope Specifies requirements of irrigation syringes also known as 'Tomey Syringes' used fo stomach and bladder irrigation in medical field.
- 1.1 For general requirements the provisions covered in IS: 82351980 'General requirements for syringes for medical use (first revision)' shall apply unless otherwise stated in this standard.
- 2. Size and Dimensions of syringes
- **2.1** Except the frontal and nozzle Portion, typically the syringes shall be as shown in Fig. 1A of 1S:3236-1980 'Specification for hypodermic syringes for general purposes (first revision)'.
- 2.2 The capacities of syringes shall be 20 ml, 80 ml and 50 ml in accordance with Table 1 of is: 3236-1980.
- 2.3 The sub-divisions or scale intervals, length of scale, the minimum length of graduation and the numbering of the graduation shall be in accordance with 8.8 and 8.4 read with Table 1 of IS:3236-1980.
- 2.4 Dimensions of syringes shall be in accordance with 3.5 read with Table 2 of [S:3236-1980 except:

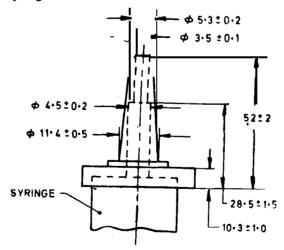
Maximum length: for 20 ml is 190 mm

for 80 ml is 210 mm for 60 ml is 280 mm

Diameter of effluent for all shall be 3.5 ± 0.1 mm.

3. Requirements

3.1 The nozzle dimension and frontal portion of the syringe shall be as shown in Fig. 1, The metallic nozzle shall tightly fit to the syringe barrel.



All dimensions In millimetres.

FIG. 1 DIMENSIONS OF NOZZLE OF IRRIGATION SYRINGE

3.2 The numbering of scale intervals shall be in accordance with col 6 of Table 1 of IS:3236-1980. The number shall be close to, but shall not touch the ends of the graduation mark to which it relates. The numbering shall generally be according to the details given in Fig. 8 of IS: 8286.1980. The numbers shall be clearly defined, durable and easily legible.

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Gr 2

IS: 6237 (Part 6) - 1666

3.3 The piston shall be easily visible through the barrel and the fiducial line shall be capable of being judged against the graduations very accurately.

4. Tests

- 4.1 All tests given in IS: 32381980 except 8.1 and 8.8.2 shall apply.
- 5, Marking Each syringe shall be legibly and durably marked with the following:
 - a) Manufacturer's name, initials or recognized trade-mark;
 - b) Unit of capacity, ml; and
 - c) Means of identification of barrel and piston.
- **5.1** Certification Marking Details available with the Bureau of Indian Standards.
- Packing Shall be as agreed to between the manufacturer and the purchaser.
- 7, Sampling -Sampling scheme and criteria for acceptance shall be as agreed to between the manufacturer and the purchaser. However, a recommended sampling plan is given in Appendix A.

APPENDIX A

(Clause 7)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1, Lot

A-I.1 In any consignment, all the syringes produced from the same material of the same type, shape and dimension under similar conditions shall constitute a lot.

A-I.2 The number of syringes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

	TABLE 1 SCALE OF SAMPL	ING	
Lot Size	Sample Size	Sub-Sample Size	
(1)	(2)	(3)	
up to 100	5	5	
101 to 150	8	5	
151 to 500	13	8	
501 to 1 000	20	13	
1 001 to 10 00 0	3 2	18	
10 001 and above	50	20	

A-1.2.1 These syringes shall be selected from the lot at random and in order to ensure the randomness of selection procedures given in IS: 49051968 'Methods for random sampling' may be followed.

A-2, Number of Tests and Criteria for Conformity

- A-2.1 All the syringes selected at random in accordance vuith col 1 and 2 of Table 1 shall be tested for dimensions, capacity, shock test, leakage test, test for entrapped fluid and freedom from striae and strain. A syringe shall be considered as defective if it fails to meet any one or more of these requirements. A lot shall be considered as conforming to these requirements if none of the syringes in the sample is found to be defective in any of these tests.
- A-2.2 If the lot is found to be conforming to the requirements given in A.2.1, the test for corrosion, permanency of marking, dry heat test and alkalinity test shall be carried out on the sub-samples selected according to col 3 of Table 1. A lot shall be considered as conforming to these requirements if none of the syringes in the sub-sample fails to meet any of these requirements.
- A-2.3 The lot shall be considered as conforming to the standard if A-2.1 and A-2.2 are satisfied.

EXPLANATORY NOTE

IS: 3237 was first published in 1965 and revised in 1989. It had then covered hypodermic syringes of small capacity, namely, insulin syringes, tuberculin syringes and BCG syringes. In the second revision of the standard undertaken in 1985, these special purpose syringes were covered in three separate" parts. Subsequently, other special purpose syringes have also been added to this standard as its further parts as given below:

IS: 3237 (Part 1)-1935 Insulin syringes (second revision)
IS: 3237 (Part 2)-1985 Tuberculin syringes (second revision)
IS: 3237 (Part 3)-1985 BCG syringes (second revision)
IS: 3237 (Part 4)-1986 Vaccine syringe
IS: 3237 (Part 5)-1986 Post operation care syringe
IS: 3237 (Part 7)-1986 Forced feeding syringe
IS: 3237 (Part 8)-1986 Angiography syringe.